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EXAMINER	
CELSA, BENNETT M	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,914	STAHLER ET AL.	
	Examiner	Art Unit	
	Bennett Celsa	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/13/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *7,8 and 12-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-11 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/04 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

It is noted that rejections of record have been modified (and new rejections raised) in response to the amended invention. It is believed that the modified rejection(s) below address all of applicant's arguments previously relied upon in the after-final amendment.

Status of the Claims

Claims 1-36 are currently pending.

Claims 1-6, 9-11 and 34-36 are under consideration.

Claims 7-8 and 12-33 are withdrawn from consideration as being directed to a nonelected invention.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-11) in Paper No. 9 Applicant's further election with traverse of nucleotides as the elected species which reads on claims 1-6 and 9-11 and 34-36 in Paper No. 9 is again acknowledged

Outstanding Objection(s) and/or Rejection (s)

Claim Rejections - 35 USC § 102 and103

Claims 1-6, 11 and 34-36 are rejected under 35 U.S.C. 102(a,b,e) as being anticipated, or in the alternative as obvious over Winkler et al. 5,677,195.

The presently claimed (e.g. claim 1) invention is drawn to: A method for producing a support for determining analytes, comprising the steps of

(a) providing a support comprising at least one channel, comprising a *fluid tight* conduit *with a top, a bottom and two sides* having an inlet and an outlet for passing fluid from the inlet to the outlet, in the support body,

(b) passing liquid with building blocks for synthesizing polymeric receptors through the channel or channels of the support body,

(c) site- and/or time-specifically immobilizing the receptor building blocks in each case on predetermined positions in the channel or channels by illumination and

(d) repeating steps (b) and (c) until the required receptors have been synthesized in each case on the predetermined positions.

Winkler teaches the syntheses of polymer (e.g. peptides or oligonucleotides) substrate arrays for use in screening studies for determination of binding affinity e.g. "for

determining sample analytes" (e.g. see Winkler Abstract; col. 1, especially lines 10-20) comprising the steps of:

(a) providing a "support" comprising at least one channel (arranged on at least one surface anticipating claim 3) comprising a conduit having an inlet and an outlet for passing fluid from the inlet to the outlet (e.g. see Winkler figures 4-8, especially figures 5-7 and col. 11-12).

(b) passing liquid with building blocks (e.g. amino acids/nucleic acids) for synthesizing polymeric (e.g peptides/oligonucleotides) receptors through the channel or channels of the support body (e.g. see Winkler figures col. 10-11);

(c) site and/or time specifically immobilizing the receptor building blocks in each case on predetermined positions in the channel or channels by illumination (e.g. see Winkler col. 1, 13-15, 25-26 and patent claims) and

(d) repeating steps (b) and (c) until the required receptors have been synthesized in each case on the predetermined positions. See e.g. Winkler col. 1, 13-15, figures, examples and patent claims. The Winkler reference method can attach the receptor species in a homogenous manner (e.g. identical species) or heterogenously (e.g. nonidentical species) thus anticipating claim 2. The Winkler reference teaches a large number of preferably parallel channels. See e.g. figure 4 and col. 11. The reference clearly teaches the syntheses of nucleic acid (and analogs) anticipating claims 5 and 6; and patent claims .

The Winkler reference channels comprise a substrate that provides " a three dimensional surface area for syntheses" (e.g. see figures); contain a plurality of different

polymer receptors {e.g. see col. 2; col. 3 (" In a preferred embodiment, a plurality of reaction regions on the substrate") and patent claims} anticipating claims 35 and 36. Additionally, the reference substrate can exist as "capillaries" (e.g. see col. 10, especially lines 14-25) wherein the substrate is a capillary channel (anticipating claim 34) which contains a 3D reactive surface (anticipating claim 36).

The Winkler reference teaches a "fluid tight conduit with a top, a bottom and two sides" since:

i. the reference figures disclose channels possessing top/bottom/2 sides (e.g. figures, especially figures 16a-b: numbers 704/705); and/or

ii. the patent claims teach "at least partially comprising $1^{st}/2^{nd}/3^{rd}$ walls which form fluid tight seals" (e.g. patent claim 1); and/or

iii. the reference channel embodiments include substrates comprising "tubing" and "capillaries" (e.g. see col. 10, lines 15-27). In this respect, the reference teaches that:

"In some embodiments, the substrate itself" which contains "... flow through regions ... form all or part of the syntheses regions" (bottom of col. 6) wherein the "substrate" "may be "... tubing .... capillaries" of various shapes (e.g. sphere, rectangle, circle) (e.g. see col. 10, lines 14-30) in which the substrate in preferred embodiments can be comprised of glass, pyrex, quartz, silicon (e.g. transparent materials) (e.g. see col. 14, especially lines 45-55).

The Examiner's rationale that a small reference genus (e.g. of substrates) can serve to either anticipate or alternatively render obvious a species (e.g. tubing and/or capillaries) under 35 USC 102 or 103 is consistent with both sound legal precedent and

PTO practice. See e.g. *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978); MPEP 2131.02; MPEP 2144.08.

Claims 1-6, 9-11 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler '195 and Fodor et al. WO 92/10092 (6/92) incorporated by reference in the Winkler '195 patent reference.

The presently claimed (e.g. claim 1) invention is drawn to: A method for producing a support for determining analytes, comprising the steps of

(a) providing a support comprising at least one channel, comprising a *fluid tight* conduit *with a top, a bottom and two sides* having an inlet and an outlet for passing fluid from the inlet to the outlet, in the support body,

(b) passing liquid with building blocks for synthesizing polymeric receptors through the channel or channels of the support body,

(c) site- and/or time-specifically immobilizing the receptor building blocks in each case on predetermined positions in the channel or channels by illumination and

(d) repeating steps (b) and (c) until the required receptors have been synthesized in each case on the predetermined positions.

Winkler teaches the syntheses of polymer (e.g. peptides or oligonucleotides) substrate arrays for for use in screening studies for determination of binding affinity e.g. "for determining sample analytes" (e.g. see Winkler Abstract; col. 1, especially lines 10-20) comprising the steps of:

(a) providing a "support" comprising at least one channel (arranged on at least one surface anticipating claim 3) comprising a conduit having an inlet and an outlet for passing fluid from the inlet to the outlet (e.g. see Winkler figures 4-8, especially figures 5-7 and col. 11-12).

(b) passing liquid with building blocks (e.g. amino acids/nucleic acids) for synthesizing polymeric (e.g peptides/oligonucleotides) receptors through the channel or channels of the support body (e.g. see Winkler figures col. 10-11);

(c) site and/or time specifically immobilizing the receptor building blocks in each case on predetermined positions in the channel or channels by illumination (e.g. see Winkler col. 1, 13-15, 25-26 and patent claims) and

(d) repeating steps (b) and (c) until the required receptors have been synthesized in each case on the predetermined positions. See e.g. Winkler col. 1, 13-15, figures, examples and patent claims. The Winkler reference method can attach the receptor species in a homogenous manner (e.g. identical species) or heterogenously (e.g. nonidentical species) thus anticipating claim 2. The Winkler reference teaches a large number of preferably paralled channels. See e.g. figure 4 and col. 11. The reference clearly teaches the syntheses of nucleic acid (and analogs) anticipating claims 5 and 6; and patent claims .

The Winkler reference channels comprise a substrate that provides " a three dimensional surface area for syntheses" (e.g. see figures); contain a plurality of different polymer receptors (e.g. see col. 2; col. 3 (" In a preferred embodiment, a plurality of reaction regions on the substrate") and patent claims) anticipating claims 35 and 36.

Additionally, the reference teaches that the reference substrate can exist as "capillaries" (e.g. see col. 10, especially lines 14-25) wherein the substrate is a capillary channel (anticipating claim 34) which contains a 3D reactive surface (anticipating claim 36). The Winkler reference teaches a "fluid tight conduit with a top, a bottom and two sides" since:

i. the reference figures disclose channels possessing top/bottom/2 sides (e.g. figures, especially figures 16a-b: numbers 704/705); and/or

ii. the patent claims teach "at least partially comprising $1^{st}/2^{nd}/3^{rd}$ walls which form fluid tight seals" (e.g. patent claim 1); and/or

iii. the reference channel embodiments include substrates comprising "tubing" and "capillaries" (e.g. see col. 10, lines 15-27). IN this respect, the reference teaches that "In some embodiments, the substrate itself" which contains "... flow through regions, etc. which form all or part of the syntheses regions" (bottom of col. 6) wherein the "substrate" "may be "... tubing .... capillaries" of various shapes (e.g. sphere, rectangle, circle) (e.g. see col. 10, lines 14-30) in which the substrate in preferred embodiments can be comprised of glass, pyrex, quartz, silicon (e.g. transparent materials) (e.g. see col. 14, especially lines 45-55).

The Examiner's rationale that a small reference genus (e.g. of substrates) can serve to either anticipate or alternatively render obvious a species (e.g. tubing and/or capillaries) under 35 USC 102 or 103 is consistent with both sound legal precedent and PTO practice. See e.g. *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978); MPEP 2131.02; MPEP 2144.08.

The Winkler et al. reference method differs, from the presently claimed invention (e.g. claims 9 and 10) for failing to explicitly teach the use of a "programmable light source matrix" for illumination (present claim 9) and computer program patterning of polymeric receptors (present claim 10).

However, the Winkler et al. patent reference teaches that the Fodor method technique of WO 92/10092 (incorporated by reference) is "an elegant method ... for using a computer-controlled system to direct a VLSIPS ™ procedure (e.g. see Winkler patent at col. 1-2, especially col. 2, lines 1-10). The Fodor method employs a computer programmable light source matrix in order to determine the pattern of polymeric receptor(s)/ligand(s) binding . E.g see Fodor at pages 22-29; examples and claims.

Accordingly, the Winkler et al. patent reference provides motivation to one of ordinary skill in the art to employ the Fodor automated light strategy in order to achieve an elegant screening technique.

Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to modify the Winkler patent teaching to employ the Fodor method use of a (computer) programmable light source matrix in order to determine the pattern of polymeric receptors in an elegant manner.

Claims 1-6, 9-11 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler '195 alone or combined with Fodor et al. WO 92/10092 (6/92) incorporated by reference in the Winkler '195 patent reference as applied to claims 1-6, 9-11 and 34-36 above, and, if necessary, further in view of Yeung et al. US Pat. No. 5,741,411 (4/98: filed 5/95).

The teaching of Winkler '195 alone and further in view of the WO 92 as described in the above 102 and 103 rejections are hereby incorporated by reference in its entirety.

To the extent that newly presented claims 34 and 36 are directed to selection of a channel possessing a 3D reactive surface (e.g. a capillary channel) the Yeung et al. patent reference is offered as providing further motivation to one of ordinary skill in the art to utilize said 3D channels in the Winkler '195 method since Yeung et al. disclose and claim the *advantageous* use of parallel capillary (having a fluid inlet/outlet) arrays in optical computerized screening of analytes in the DNA context (e.g. using CID/CCD). See Yeung, abstract, disclosure and particulary patent claims.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art the time of applicant's invention to utilize a capillary substrate system in the Winkler '195 method in view of the Winkler reference enumeration of a capillary among a small list of possible substrate reaction surfaces as a preferred substrate and, if necessary, further in view of the assay screening advantages in the DNA setting of utilizing such substrates as further taught by the Yeung et al. reference.

New Objection (s) and/or Rejection (s)

Claim Objections

Claim 6 is objected to because of the following spelling: "olignuclectides". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 9-11 and 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The term "large number of channels" in claim 4 is a relative term which renders the claim indefinite. The term "large number" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

b. The term "fluid tight" in claim 1 (and claims dependent thereon) is a relative term which renders the claim indefinite. The term "fluid tight" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

c. In claim 1 (and claims dependent thereon), the phrase "the support body" lacks antecedent basis.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9-11 and 34-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (e.g. NEW MATTER REJECTION).

The After-Final amendment entered with the filing of the present RCE application (dated 11/13/04) amended claim 1 to recite "... a support ... comprising a **fluid tight** conduit with a top, a bottom and two sides having an inlet and an outlet..." (newly added limitation in bold) citing support in the device depicted in Fig. 3 without further explanation.

Upon review of the specification, the Examiner was unable to find explicit support for the above added bolded limitation. Additionally, the drawing did not provide support for the term "fluid tight". There is nothing in the drawing that indicates that the conduit is "fluid tight" since there is no indication of the degree of porosity of the depicted support and/or whether liquid introduced into the channels would drip and/or leak out at any portion of the depicted channels. Additionally, the term "fluid tight" is relative and the degree of fluid leakage is a function of different variables (e.g. support chemical composition) none of which can be determined from the figure.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 9-11 and 34-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,586,211.

The presently claimed (e.g. claim 1) invention is drawn to: A method for producing a support for determining analytes, comprising the steps of

(a) providing a support comprising at least one channel, comprising a *fluid tight* conduit *with a top, a bottom and two sides* having an inlet and an outlet for passing fluid from the inlet to the outlet, in the support body,

(b) passing liquid with building blocks for synthesizing polymeric receptors through the channel or channels of the support body,

(c) site- and/or time-specifically immobilizing the receptor building blocks in each case on predetermined positions in the channel or channels by illumination and

(d) repeating steps (b) and (c) until the required receptors have been synthesized in each case on the predetermined positions.

The Stahler patent claims teach a method for producing polymers by attaching "oligomeric building blocks" (e.g.nucleic acid fragments; i.e. natural nucleotides and/or modified nucleotides: see patent claims 1, 6, 16) by parallel syntheses on different areas of a common support "for specific interaction with other molecules" (e.g. "determining analytes: see patent claim 11) wherein the "building blocks" or nucleic acid fragments" are "synthesized by location and/or time resolved illumination by means of a programmable light source matrix" (e.g. patent claims 6, 14). The patent claims encompass the use of "microfluidic reaction support" (e.g. see patent claim 15: i.e.fluid movement of reagents) which include comprising at least one channel, comprising a *fluid tight* conduit *with a top, a bottom and two sides* having an inlet and an outlet for passing fluid from the inlet to the outlet, in the support body. See e.g. Patent Fig. 5 and incorporation of supports encompassed by PCT/EP99/06317 (WO00/13018) which is the parent of the present application (e.g. see col. 4-5 and 9-10).

Claims 1-6, 9-11 and 34-36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31-60 of copending Application No. 10/399,450.

The application claims are drawn to A method for integrated syntheses and analyte determination on a support (e.g. application claims 31-46) and an apparatus for

carrying out the method (e.g. application claims 47-60) which references figure identifiers (e.g. figures 1-17) which teaches

(a) providing a support comprising at least one channel, comprising a *fluid tight* conduit *with a top, a bottom and two sides* having an inlet and an outlet for passing fluid from the inlet to the outlet, in the support body {e.g. see application claims 31(step a), 44, 47("support body"), 48 and figures, especially figures 3A, 15-17 and "multiplicity of (inner)channels" (40)} ,

(b) passing liquid with building blocks for synthesizing polymeric receptors through the channel or channels of the support body (E.g. see steps b-d, especially d of claim 31; and and "means for supplying receptors or receptor building blocks" in apparatus of application claim 47),

(c) site- and/or time-specifically immobilizing the receptor building blocks in each case on predetermined positions in the channel or channels by illumination (e.g. see step (e) of claim 31 and claims 55-60);

(d) repeating steps (b) and (c) until the required receptors have been synthesized in each case on the predetermined positions (see claim 31 step f).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 101

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-6, 9-11 and 34-36 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-6, 9-11 and 34-36 of copending Application No. 10/727,566. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Further Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-273-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639

BC
November 5, 2004